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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/014,087 01/27/98 CARLYLE

W 07001/065001

EXAMINER

QM12/0526

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PREBILIC, P

ART UNIT	PAPER NUMBER
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3738

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DATE MAILED:

05/26/00

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>09/014,087</b>	Applicant(s) <b>Carlyle et al</b>
	Examiner <b>Paul Prebilic</b>	Group Art Unit <b>3738</b>

Responsive to communication(s) filed on Apr 4, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-11, 14, 15, and 21-28 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-11, 14, 15, and 21-28 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on Dec 6, 1999 is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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*Drawings*

The corrected or substitute drawings were received on December 6, 1999. These drawings are approved.

*Claim Rejections Based Upon Prior Art*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Guire (US 5,263,992) wherein the human tissue of Guire is an allograft tissue by definition and the growth factors of Guire are bound covalently with a linker molecule; see the whole document, especially Col. 3, line 65 to Col. 4, line 50.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-8, 25, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guire (US 5,263,992) in view of Carpentier et al (US 4,648,881).

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With regard to claims 5, 6, 25, 27, and 28, Guire meets the claim language except for the use of crosslinked or uncrosslinked tissue as a base material as claimed. Carpentier et al, however, teaches that it was known to the art to use either crosslinked or uncrosslinked tissue as an implant material; see the whole document, especially Col. 3, lines 11-15. Hence, it is the Examiner's position that it would have been obvious to use crosslinked tissue to reduce host organism rejection risk or to use uncrosslinked tissue to maintain the elastic properties of the tissue when such is needed in the Gurie invention.

With regard to claims 7, 8, 27, and 28, Guire meets the claim language but uses human tissue instead of porcine heart valve or bovine pericardial tissue as claimed. Carpentier et al, however, teaches that it was known to the art to use porcine heart valve or bovine pericardial tissue. Hence, it is the Examiner's position that it would have been obvious to use either tissue for the human tissue of Guire in order to reduce the cost of the implant and in order to reduce the risk of transmitting a human-specific diseases to a human patient.

Claims 9, 10, 14, 15, 21-24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guire and Carpentier et al as applied to claims 5-8, 25, 27, and 28 above, and further in view of Tisher (US 5,194,596). Guire discloses the use of various growth factors with the implant thereof but fails to disclose the use of vascular endothelial growth factor as claimed. Tisher, however, teaches that it was known to the art to use vascular endothelial growth factor with implants. Hence, it is the Examiner's position that it would have been obvious to an ordinary

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artisan to use vascular endothelial growth factor as the growth factor of Guire's invention when applied to the vascular region in order to better promote cell growth in that particular area of use.

With regard to claim 24 specifically, the synthetic polymer as claimed reads on a crosslinked treated tissue which is synthetic or man-made once it is cross-linked.

*Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vincent Millin, can be reached on (703) 308-1065. The fax phone number for this Technology Center is (703) 305-3580.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic  
Primary Examiner  
Art Unit 3738